



Docket No. 4517-4002

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Raya LEVIN, et al.

Group Art Unit: 1754

Serial No.: 10/631,923

Examiner: LISH, Peter J.

Filed: July 31, 2003

For: CALCIUM CARBONATE GRANULATION

DECLARATION UNDER 37 C.F.R. § 1.132

I, Dr. Gregory Urbanski, declare that:

1. I hold a Ph.D. degree in food science from the University of Illinois (1981).
2. I have 25 years of work experience in the food and dietary supplement industries.

I have worked at Quaker Oats Company (1981-1983); Express Dairy Foods (1983-1984); Wyeth, Nutritional Division (1984-1991); Kraft/Best Foods/Westin Baking Companies (1991-2002); and Bimbo Bakeries U.S.A. (Vice President of Research and Development, 2002-2004).

3. Currently, I am the Vice President of Technology at Delavau, LLC, the assignee of United States Patent Application Serial No. 10/631,923.

4. Much of my work experience has involved techniques for drying powdered materials, including milk proteins (Express Dairy Foods), infant formulas (Wyeth), and nutritional supplements (Delavau, 2004-present).

5. At Kraft/Best Foods/Westin Baking Companies, my duties and expertise included bakery ovens. I was awarded the Kraft "Superior Achievement Award" in 1994 and the Best Foods "Chairman's Award" in 1996.

6. I have read and understand U.S. Patent Application Ser. No. 10/631,923 ("the '923 application"), entitled "Calcium Carbonate Granulations" and I submit this Declaration in its support.

7. I have read and understand the Office Action dated January 18, 2006 and the Gennaro reference (Remington: The Science and Practice of Pharmacy, Nineteenth Ed., Vol. II, pp. 1623-1625) cited by the Examiner.

8. It is my opinion that Gennaro does not teach or suggest a "process for preparing high density granulation comprising the steps of: (1) mixing a composition in a high shear mixer; and (2) drying the composition in a horizontal fluidized bed oven," as required by the amended claims of the '923 application. The basis of my opinion is set forth below.

9. Gennaro states that "[w]hile tray drying was the most widely used method of drying tablet granulations in the past, fluidized-bed drying is now equally popular. Notable among the newer methods being introduced are the fluid-bed dryers" [p. 1626].

10. One skilled in the art of granulation and drying would understand that Gennaro's reference to "fluid-bed dryers" relates solely to a particular type of fluid-bed dryer commonly known as a vertical fluidized-bed. This is clear from Figure 12 of Gennaro which illustrates three common vertical "fluidized-bed granulation and drying" systems, labeled A, B and C. (p. 1624). Each apparatus in Figure 12 comprises a vertical chamber of cylindrical design in which

the material to be granulated or dried is suspended "in a vertical column with a rising air stream" (p. 1625).

11. The pending claims of the '923 application require a "horizontal fluidized bed oven." Horizontal fluidized-bed ovens are very different from the vertical fluidized beds described in Gennaro in design, operation, and result.

12. Examples I-VI of the '923 application describe using a "Carrier model QAD/C 1260 S horizontal fluidized bed" to dry granulated calcium carbonate. The Carrier model QAD/C 1260 S horizontal fluidized bed oven is illustrated in Appendix A. This illustration is taken from the operating manual for the model QAD/C 1260 S oven prepared by the Carrier Corporation.

13. The Carrier model QAD/C 1260 S horizontal fluidized bed oven comprises a perforated deck along which the granulation is fluidized transversely with respect to the direction of flow primarily by vibration. The granulation is displaced from the deck only minimally by the fluidizing action of the vibrating lower deck. In contrast to the vertical fluidized beds, the granulate is fluidized primarily by vibration rather than by a forced flow of air. Also, drying in horizontal fluidized bed oven is accomplished primarily by convection of warm air rather than the forced flow of heated air.

14. The inventors of the '923 application have found that the density of granulation obtained by drying in a horizontal fluidized bed oven is substantially greater than that obtainable in a vertical fluidized bed dryer, such as those described in Gennaro. I consider this to be a surprising result because it is generally known in the art that vertical fluidized bed drying tends to reduce the density of the granulation. For example, Gennaro states that "[r]esearchers have

observed that, in general, fluidized bed granulation yields a less dense particle than conventional methods, and this can affect subsequent compression behavior." (p. 1625). One skilled in the art would therefore not have been motivated to select fluidized bed drying methods where the goal is to achieve high density granulation.

15. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-referenced application or any patent issuing thereon.

05/17/2006

Date



Dr. Gregory Urbanski

APPENDIX A

